

Notice of Allowability

Application No.

10/009,919

Applicant(s)

PANACCIO ET AL.

Examiner

Padmavathi v. Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/28/05.
2. ☒ The allowed claim(s) is/are 1, 2 and 4 have been renumbered as 1-3 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Interview Summary (PTO-413), Paper No./Mail Date 10/14/05 & 10/17/05.
- ☒ Examiner's Amendment/Comment
- ☐ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

DETAILED ACTION

1. Applicant's after final amendment filed on 9/28/05 is acknowledged and entered.

Status of Claims

2. Claims 1-4 have been amended.

Claims 5-48 are canceled.

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kenneth Kohn and Andrew Parial on 10/14/05 and 10/17/05.

Claim 1: (currently amended) A recombinant immunogenic polypeptide ~~comprising~~ consisting of the amino acid sequence SEQ ID NO. 1.

Claim 2: (currently amended) The recombinant immunogenic polypeptide of claim 1 wherein said Polypeptide elicits the production of antibodies against *Lawsonia spp intracellularis* when administered to an avian or porcine animal.

Claim 3 has been canceled.

Claim Rejection - 35 U.S. C. 112, first paragraph moot

3. In view of cancellation of claims 21 and 23, the first paragraph enablement rejection under U.S.C. 112, first paragraph is moot .

Claim Rejections - 35 USC § 102 withdrawn

4. In view of amendment of claims 1-2, the rejection under 35 U.S.C. 102(b) as being anticipated by McOrist et al, Infect Immun. 1989 March; 57 (3): 957-962 as evidenced by

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McOrist et al 1995 Int J Syst Bacteriol 1995 Oct; 45(4): 820-5 is withdrawn as the prior art does not disclose the claimed recombinant polypeptide.

Remarks

5. The instant claims define a novel recombinant immunogenic polypeptide consisting of the amino acid sequence SEQ.ID.NO: 1. Genomic DNA was extracted from percoll-gradient purified *Lawsonia intracellularis* bacteria recovered from infected pig ilea. The disclosed recombinant polypeptide is obtained by immuno screening phage library using sera obtained from the pigs Y12 and 395 that had previously been immunized with formalin-killed *L. intracellularis* and heat-killed *L. intracellularis*, respectively. The amino acid sequence of this hemolysin polypeptide is unique and novel and is neither disclosed nor suggested by prior art, McOrist et al. The claimed polypeptide SEQ.ID.NO1 is immunogenic and therefore it could be used as a diagnostic agent, or as a candidate therapeutic agent for treatment of intestinal disease, porcine proliferative enteropathy (PPE) in pigs and birds caused by *Lawsonia intracellularis*.

6. Claims 1, 2 and 4 are allowed and have been renumbered as 1-3 respectively.

Conclusion

7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

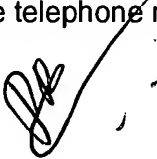
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D

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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Claim 1: (currently amended) A recombinant immunogenic polypeptide consisting of the amino acid sequence SEQ ID NO. 1.

Claim 2: (currently amended) The recombinant immunogenic polypeptide of claim 1 wherein said polypeptide elicits the production of antibodies against *Lawsonia intracellularis* when administered to an avian or porcine animal.

Claim 3 has been canceled.

³
Claim ~~4~~: The recombinant immunogenic polypeptide of claim 1 wherein the polypeptide is a recombinant form of *Lawsonia intracellularis*.